U.S. Patent No. 8,153,162; 8,182,840; 8,182,841; 8,187,639; 8,420,126; 8,440,235; 8,455,009; 8,460,714

PRODUCT INSERT

DESCRIPTION

NEOX FLO is a sterile, particulate human placental tissue product. **NEOX FLO** is aseptically processed in compliance with current Good Tissue Practices (cGTP) from Amniotic Membrane and Umbilical Cord tissues obtained from donated human placental tissue after determination of eligibility and placenta/cord suitability. Processing retains key biological characteristics of the tissue. **NEOX FLO** is stored in vials for suspension and packaged in a pouch. **NEOX FLO** is terminally sterilized via gamma sterilization with a Sterility Assurance Level (SAL) of 10^{-6}.

INDICATION

- **NEOX FLO** can be used as a wound covering for dermal ulcers or defects.
- **NEOX FLO** is for single use in 1 patient only by a licensed physician or qualified medical professional (e.g. PA, NP).

PRECAUTIONS

- Do not use **NEOX FLO** if the packaging is damaged - Contact Amniox Medical, Inc. immediately if there is any abnormality observed in any area (e.g. labeling, packaging, shipping, missing information, etc.).
- Once the outer pouch is opened, **NEOX FLO** shall either be transplanted or otherwise discarded.
- Suspend and remove **NEOX FLO** only at the time of use. No expiration time following reconstitution.
- Do not re-sterilize the product. Do not autoclave before use.

WARNINGS

As with the use of any human tissue, the possibility of infectious agent transmission cannot be completely eliminated although all screening and microbial testing results were satisfactory for this donor.

STORAGE

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Upon receipt, ensure the shipper is within the validated time indicated on the shipper. Remove the tissue and store accordingly until use:

LOCATION & TEMPERATURE	USE AFTER RECEIPT
Ambient Room Temperature 0°C → 38.0°C (32.0°F → 100.4°F)	Until the expiration date printed on outer product packaging (shelf-life is 2 years from date of manufacture)

INSTRUCTIONS

1. Open the pouch to retrieve the **NEOX FLO** vial. Vial can be delivered to a sterile field.
2. To use in dry form, remove the cap of the vial. Apply or deliver particulate placental tissue with sterile surgical tool.
3. To suspend for injection, first remove the cap from the vial. Aseptically transfer approximately 0.5-2.0 mL of normal saline or sterile USP injection water into the vial with an 18-25 gauge needle. Shake the vial for at least 45 seconds to achieve a homologous mixture. Aseptically withdraw the mixture with a syringe and an 18- 25 gauge needle.
   After transplantation, complete the Donor and Recipient Information (DRI) Card and return to Amniox Medical, Inc.

See Reverse

DONOR ELIGIBILITY AND SUMMARY OF RECORDS

- This tissue was procured from a donor determined to be eligible based on the results of screening and testing. HCT/P donor eligibility and placenta suitability, which is based on the results of donor screening at delivery for infectious, malignant, neurological & auto-immune diseases and for other exposures or social habits, has been determined and documented by TissueTech, Inc.
- A blood specimen, drawn within ± 7 days of donation, has undergone serological testing by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). The donor has been tested for the following infectious diseases and results were non-reactive:

  — HIV-1 & HIV-2 Antibody
  — HIV-1 (RNA-NAT)
  — Hepatitis B Surface Antigen (HBsAg)
  — Hepatitis B Core Antibody (HBcAb)
  — Hepatitis B (HBV, DNA-NAT)
  — Hepatitis C Antibody (HCVAb)
  — Hepatitis C Virus (HCV, RNA-NAT)
  — Syphilis (RPR)
  — HTLV I & II Antibody (HTLV I/II Ab)
  — West Nile Virus (WNV, RNA-NAT)

- This tissue has been deemed eligible for transplantation based on acceptable screening, serological and microbial test results.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for Amniox Medical products is available upon request.

RECIPIENT RECORDS

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain records for the purpose of tracing tissue post-transplantation. The transplanting entity should document the disposition (transplanted or discarded) on the Donor and Recipient Information Card (DRI), attach one of the provided product tracking labels to the DRI and mail to Amniox Medical. Attach the remaining labels in patient and hospital records.

CUSTOMER FEEDBACK

Within the United States: Report any customer feedback, including complaint, error or accident notification promptly to Amniox Medical at (888) 709-2140.
Outside of the United States: Report feedback to your local tissue provider.

ADVERSE EVENT

The FDA requires that information be supplied to the product manufacturer for mandatory reporting of adverse events. Possible significant adverse events include microbial infection and transmission of viral disease. **The doctor is responsible for immediately reporting any adverse event potentially attributable to the use of NEOX 100 to Amniox Medical.**

For ADVERSE EVENT complete the following section. Notify via:
Phone: (888) 709-2140
Fax: (305) 675-3262
Email: Customerfeedback@amnioxmedical.com

Serial Number: _____

Expiration Date: ___ / ___ / ___

Doctor Name: _____

Facility Name: _____

Transplant Date: ___ / ___ / ___

Diagnosis/Procedure: _____

Site of Use: _____

Point of Contact's Name: _____

Point of Contact's Phone Number: ____ / ____ / _____

Date Adverse Event was Reported: _____

Type of Adverse Event:
☐ Microbial Infection ☐ Transmission of Viral Disease ☐ Other

Describe the Adverse Event: _____

_____

_____

amniox® MEDICAL

Manufactured for Amniox Medical, Inc. by TissueTech, Inc.
8305 NW 27th St, Suite 101, Doral, Florida 33122 USA
(888) 296-8858

FEI #: 3009809074
PI-AX-003E, V2